

Food and Drug Administration
Center for Drug Evaluation and Research
Oncologic Drugs Advisory Committee Meeting
FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center
(Rm. 1503), Silver Spring, MD
March 20, 2012

DRAFT QUESTION

NDA 022576
Taltorvic (ridaforolimus) tablets

APPLICANT: Merck Sharp & Dohme Corp.

PROPOSED INDICATION: To treat patients with metastatic soft tissue sarcoma or bone sarcoma whose disease has not progressed after at least 4 cycles of chemotherapy.

VOTE: Has a favorable risk-benefit profile for ridaforolimus as a maintenance therapy for patients with metastatic soft tissue or bone sarcoma who have stable disease or better after 4 or more cycles of chemotherapy been demonstrated?